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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,152	02/26/1999	KENICHI HIGASHIYAMA	001560-344	6530

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	23

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/254,152	Applicant(s) HIGASHIYAMA ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13, 14.29,30,32-36,47-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,14,29,30,32-36 and 47-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted January 16, 2003 is acknowledged.

Claim Rejection 35 USC – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13, 14, 29, 30, 32-36 and 47-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmen et al (of record) in view of both of Shimizu et al (of record) and Barclay (of record).

Shinmen et al. teach an unsaturated fatty acid-containing oil obtained from culturing of microorganism *Mortierella* contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen also teach the nutritive effect of arachidonic acid. See, particularly, the introduction on page 11.

Shinmen et al. do not teach how much of 24,25-methylenecholest-5-en-3β-ol is present in the oil. Shinmen do not teach the employment of such oil in food products including baby food and animal food.

However, Shimizu et al. teach that unsaturated fatty acid-containing oil obtained from culturing microorganism Mortierella has 24,25-methylenecholest-5-en-3β-ol which has not been found in nature, i.e., not found in any natural food such as breast milk and its biological activity and toxicity have not been fully evaluated. See, particularly, the abstract on page 481. Barclay

teaches the employment of arachidonic acid containing oil obtained from culturing microorganism Mortierella for food product including baby food and animal food. See, particularly, column 7, line 48-60.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the unsaturated fatty acid-containing oil of Shinmen et al. by *removing* the biologically unknown compound, i.e., 24,25-methylenecholest-5-en-3β-ol and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement.

A person of ordinary skill in the art would have been motivated to remove 24,25-methylenecholest-5-en-3β-ol from the unsaturated fatty acid-containing oil and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement *because the biological activity of 24,25-methylenecholest-5-en-3β-ol is not known and it would not be safe to use such oil in baby food.* Methods of removing the compound such as chromatography separation or modification of fermentation conditions are considered within the skill of artisan. Furthermore, employment of unsaturated fatty acid-containing oil in food products are known.

With respect to the newly added limitation, which recites the process of making the oil composition, and new claims 47-60, note "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of product does not depend on its method of production. If the product in the product-by-process claims is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the product is made by different process" (MPEP 2113). In the instant case, the claimed product possesses nothing patentably distinct from the cited prior art.

Response to the Arguments

Applicants' amendments and remarks submitted January 16, 2003 have been fully considered. The amendments and remarks are persuasive in overcome the double patenting rejections over US patent 6,117,905, but are not persuasive with respect to the rejections under 35 U.S.C. 103.

Applicants argue that cited references do not teach how to remove the 24, 25-methylenecholest-5-en-3b-ol, suggesting that one of ordinary skill in the art would have not been able to, and therefore, motivated to remove 24, 25-methylenecholest-5-en-3b-ol. These arguments are not probative. As stated in the prior office action: "A person of ordinary skill in the art would have been motivated to remove 24,25-methylenecholest-5-en-3β-ol from the unsaturated fatty acid-containing oil and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement *because the biological activity of 24,25-methylenecholest-5-en-3β-ol is not known and it would not be safe to use such oil in baby food.* Methods of removing the compound such as chromatography separation or modification of fermentation conditions are considered within the skill of artisan." Applicants' attention is directed to Shimizu et al. Shimizu et al. shows that 24,25-methylenecholest-5-en-3β-ol could be easily separated from other unsaponifiables, such as desmosterol. See Fig 1. Further, modification of fermentation conditions is certainly a valid way to meet the claimed limitation. For example, the particular fermentation method employed by Shimazu would yield an oil with less 24,25-methylenecholest-5-en-3β-ol. See, table 1.

Applicants argue unexpected results by substitute yeast extract with soybean protein in the fermentation. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The evidence must be clear and convincing, and must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.1323 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e). The instant claims are drawn to a composition, which is obvious as discussed above. The data cited by applicants is drawn to method of making the composition, which is moot to the issue discussed in the rejections. Further, there is no clear and convincing evidence showing one of ordinary skill in the art would have not been able to, and therefore motivated to make the claimed invention.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

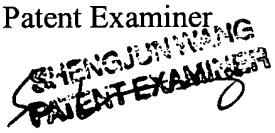
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner



Shengjun Wang

April 4, 2003